

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO WAVE 4 CASES ON EXHIBIT A TO PLAINTIFFS' MOTION</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

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**PLAINTIFFS' REPLY IN FURTHER SUPPORT OF  
DAUBERT MOTION TO PRECLUDE OR LIMIT OPINIONS OF  
DEFENSE EXPERT SARAH ABBIE COLLINS**

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## **LEGAL ARGUMENT**

### **DR. COLLINS' GENERAL OPINIONS SHOULD BE PRECLUDED OR LIMITED**

Defendants' opposition to Plaintiffs' motion focuses primarily on statements made in Dr. Collins' report, ignoring or minimizing fundamental concessions by Dr. Collins in her sworn deposition testimony – concessions that should result in the striking of virtually all of her general opinions.

Another fundamental flaw in the Defendants' opposition is the focus on Dr. Collins' qualifications as a practicing physician, which does not address the lack of objective or reliable methodologies to support the opinions. Dr. Collins' opinions can be nearly reduced to a statement based on her own practice, and for her own needs in her own practice, the devices in question were properly designed and the warnings were adequate. That is not an adequate methodology since Dr. Collins fails to reference or utilize any standards that can be objectively applied by others to test her opinions. Dr. Collins does not even know the standards that were applied by Ethicon itself in the design and warnings, and thus cannot even apply those standards in offering her opinions.

First, with regard to the warnings opinions, Defendants provide nothing to establish that Dr. Collins applied any reliable methodology or standards in offering her conclusions, which are nothing more than net opinions. Experience with the product is not enough to overcome the fatal lack of objective, reliable criteria or method to forming these opinions. As Plaintiffs' motion sets forth, Dr. Collins candidly stated that whatever risks are included in the IFU are irrelevant to her. Defendants attempt to circumvent these gaping holes in methodology by couching Dr. Collins' warnings opinions as risks that are "commonly known."<sup>1</sup> Plaintiffs' motion did—and does—seek to exclude Dr. Collins from discussing whether certain risks were commonly known

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<sup>1</sup> Defs' Mem. at 3-5.

in the medical community. Defendants attempt to argue in its response brief that Dr. Collins will not be offering opinions as to what should or should not be included in the IFU from a regulatory perspective. However, within the same breath, Defendants go on to state that Dr. Collins would “testify about complications that are ‘commonly known’ such that they need not be included in an IFU.”<sup>2</sup> In essence, even though they claim otherwise, Defendants argue that Dr. Collins should be allowed to opine that the IFU is accurate and sufficient from a regulatory perspective because, to the extent any risks were not included, those risks are commonly known to the medical community.<sup>3</sup> But, as Plaintiffs set forth in their motion, Dr. Collins has clearly admitted that she believes it to be irrelevant what risks are included in the IFU. Furthermore, she has clearly admitted that she has no definitive knowledge of the contents in any IFU except the 2015 version.<sup>4</sup> As such, Dr. Collins should be precluded from testifying that any certain risk was commonly known in the medical community. Allowing her to provide such speculative testimony would allow Ethicon to argue that it had no duty to warn of those risks.

Second, with regard to design and mesh properties opinions, Defendants ignore Dr. Collins’ concession that she lacks knowledge regarding the appropriate pore size, weight, or weave of the TVT and TVT-Exact sling devices. Specifically, as Plaintiffs’ motion sets forth, Dr. Collins testified that she is not an expert on these types of mesh properties. As such, Dr. Collins should be precluded from opining on mesh design and properties.

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<sup>2</sup> Defs’ Mem. at 4.

<sup>3</sup> Defs’ Mem. at 3-5.

<sup>4</sup> As Plaintiffs’ motion set forth, Dr. Collins recalled reviewing one other version of the IFU but did not know which version.

### **CONCLUSION**

For all of the foregoing reasons, in addition to the arguments set forth in Plaintiffs' motion, Plaintiffs' *Daubert* motion to preclude or limit the opinions of Dr. Collins should be granted.

Dated: May 4, 2017

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that I filed the foregoing document on May 4, 2017, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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